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M. Bud Nelson

Name

Signature

Date of Signature

15 Sept. 2003

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Mary K. Delmedico & John Dwyer

Application No.

Examiner:

Filed: 16 September 2003

Art Unit

For: HIV-derived HR1 peptides modified to form stable trimers, and their use in therapy to inhibit transmission of Human Immunodeficiency Virus

Commissioner for Patents  
Alexandria, VA

**Docket No. TRM-001**

**INFORMATION DISCLOSURE STATEMENT**  
**37 CFR 1.56 and 1.97**

Applicants wish to make of record the following reference under the provisions of 37 CFR 1.56 and 1.97 **and** to provide a copy of relevant background with respect to the application. The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application, or is to be considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove any document as a cited reference against the claims of the present invention.

References Cited

Please see attached Form PTO-1449 for list of publications, legible copies of all publication listed are enclosed.

Statement of Relevancy

Non Patent Literature Documents

Cites 1,2, 7, 8, and 9 generally relate to HR1 peptides.  
Cites 3, 4, 5, 6, 9, and 10 generally relate to gp41 structure.

Patent Documents

Cites 11,12, 16 & 18 generally relate to HR1 peptides.  
Cites 13, 14, 17 & 19 generally relate to modifications of HR peptides.  
Cite 15 generally relates to gp41 structures.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'M. Bud Nelson', is written over a horizontal line.

M. Bud Nelson

Reg. No. 35,300

Attorney for the Applicants

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Compleat if Known**

Application Number	
Filing Date	16 Sept. 2003
First Named Inventor	Delmedico, May Kay
Art Unit	
Examiner Name	
Attorney Docket Number	TRM-001

Sheet 2 of 2

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	11	US- 6,573,078	06-03-2003	Wild et al.	
	12	US- 20020077284	06-20-2002	Eckert et al.	
	13	US- 6,489,449	12-03-2002	Yu et al.	
	14	US- 6,348,568	02-19-2002	Barney et al.	
	15	US- 6,150,088	11-21-2000	Chan et al.	
	16	US- 5,656,480	08-12-1997	Wild et al.	
	17	US- 6,258,782	07-10-2001	Barney et al.	
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	18	WO 01/51673	07-19-2001	Trimeris, Inc.		
	19	WO 00/69902	11-23-2000	ConjuChem, Inc.		

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	
		Filing Date	16 Sept. 2003
		First Named Inventor	Delmedico, Mary Kay
		Art Unit	
		Examiner Name	
Sheet 1	of 2	Attorney Docket Number	TRM-001

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1.	WILD et al.; "A synthetic peptide inhibitor of human immunodeficiency virus replication...."; Nov. 1992; 10537-10541; vol 89; Proc. Natl. Acad. Sci. USA	
	2.	WILD et al.; "A Synthetic Peptide from HIV-1 gp41 Is a Potent Inhibitor of Virus-Mediated Cell-Cell Fusion"; Nov. 11, 1993; 1051-1053; vol 9; Mary Ann Liebert, Inc., Publishers	
	3.	CHAN et al.; "Core Structure of gp41 from the HIV Envelope Glycoprotein"; April 18, 1997; 263-273; vol 89; Cell Press	
	4.	SHU et al.; "Trimerization Specificity in HIV-1 gp41: Analysis with a GCN4 Leucine Zipper Model"; April 1999; 5378-5385; vol 38; Biochemistry	
	5.	ECKERT et al.; "Inhibiting HIV-1 Entry: Discovery of D-Peptide Inhibitors that Target the gp41 Coiled-Coil Pocket"; Oct. 1, 1999; 103-115; vol 99; Cell Press	
	6.	ROOT et al.; "Protein Design of an HIV-1 Entry Inhibitor"; Feb. 1, 2001; 884-888; vol 291; SCIENCE	
	7.	LOUIS et al.; "Design and Properties of Nccg-gp41, a Chimeric gp41 Molecule with Nanomolar ..."; Aug. 3, 2001; 29485-29489; vol 276; no. 31; Journal of Biological Chemistry	
	8.	BEWLEY et al.; "Design of a Novel Peptide Inhibitor of HIV Fusion...."; April 19, 2002; 14238-14245; vol 277; no. 16; Journal of Biological Chemistry	
	9.	LAWLESS et al.; "HIV-1 Membrane Fusion Mechanism: Structural Studies of the Interactions...."; 1996; 13697-13708; vol 35, no. 42; Biochemistry	
	10	HARBURY et al. "A Switch Between Two-, Three- and Four-Stranded Coiled Coils....."; 1993; 1401-1407; vol. 262, Science.	

Examiner Signature	Date Considered
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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